

Remarks

Claims 1-2, 4-8, 10-20, 22-26, 28-37, and 39-42 are presented for the Examiner's review and consideration. In this response, claims 1, 4, 13, 19 and 32 are amended, claims 9, 27 and 38 are canceled, and claims 40-42 are new. Applicant believes the claim amendments and the accompanying remarks, herein, serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. §103(a) Rejection

Claims 1, 2, 4-20 and 22-39 were rejected under 35 U.S.C. §103(a) as being unpatentable over Burkinshaw et al. (US 6,007,537) ("Burkinshaw") in view of Mains et al. (US 4,421,112). Initially, as noted above, claims 9, 27 and 38 have been canceled herein, rendering the rejection of these claims moot. For reasons set forth below, Applicant respectfully submits that, with respect to the remaining claims, this rejection should be withdrawn.

Claims 1, 13 and 19 are herein amended to further clarify the invention. Claims 1 and 19 have been amended to recite, *inter alia*:

replacing at least a portion of a joint, supported throughout the specification, for example at paragraph [0394] et seq., and Fig. 43;

an incision sized smaller than the portion of the knee to be replaced, supported, for example, at paragraph [0165]; and

initially cutting an unresected bone, supported for example at paragraph [0499] and Fig. 54.

Claims 13 and 19 have been clarified to recite, *inter alia*, a customized cutting guide that is no longer useful once the bone has been cut, supported at least at paragraphs [0709] and [0712], for example.

Burkinshaw

Burkinshaw discloses "a nested cutting block [including] at least a first slot for guiding a saw blade during a first bone cutting operation. The first block has a cavity formed therein. A first securing interlock is formed on the first block. A second block is detachably mounted in the cavity and includes at least a second slot for guiding the saw blade during a second bone cutting

operation.” [Abstract].

“In operation, the distal femur is prepared by first making a transverse cut along the top surface. A first anterior referencing cut may also be made.” [Col. 5, ln. 11].

Thus, Burkinshaw is not directed to a minimally invasive procedure, and particularly to a procedure where a reduced size incision is made, the incision sized smaller than a portion of the knee to be replaced. It is clear from the design and disclosure in Burkinshaw that the distal end of the femur is completely exposed, as was the norm in 1998 when Burkinshaw was filed. In addition, a first cut is made in Burkinshaw, presumably using a known method, which at the time was in intramedullary rod. More particularly, no other method is disclosed for making the first referencing cut on the femur, and in addition, the cutting block of Burkinshaw does not work unless a first referencing cut is made. Thus, Burkinshaw does not disclose a method of referencing which does not use an intramedullary rod, and requires that the femur has an initial resecting cut.

Mains

Mains discloses “a guide assembly for use in a tibial osteotomy wherein two pairs of parallel guide pins are inserted into the tibia at a predetermined angle with respect to each other through a guide block. The adjacent surfaces of the pairs of pins are then used to precisely guide a saw by which a wedge-shaped segment of the tibia is removed.” [Abstract].

“...the pins are accurately located through the use of a guide block having a first pair of spaced parallel guide bores adapted to closely receive and guide the first pair of guide pins as they are inserted into the tibia and a second pair of spaced parallel guide bores adapted to receive and guide the second pair of guide pins as they are inserted.” (Col. 2, ln. 50).

“First, (FIG. 2) the first pair of the guide pins 12 is inserted in a tibia 40 just below a knee joint 42 by rotating the pins 12 via a drill motor (not shown) through the first pair of bores 22 in the guide block 20 located so that the intersection of a plane through the axes of both pins 12 with a sagittal plane of the body is generally parallel to the plane of the knee joint 42, and the intersection of the plane through the axis of both pins 12 with a longitudinal plane of the body is generally parallel to or angled generally away from the plane of the knee joint 42 starting from the point 44 of insertion of the first pair of pins 12.” (Col. 4, ln. 57).

“...after the first pair of guide pins is inserted a desired depth into the tibia through the guide block (which depth can be determined by feeling the emergence of the tips of the pins through the curved cortical shell of the tibia) the guide block is located along the first pair of guide pins with the locating surface of the block at a relationship with respect to the locating mark along at least one of the first pair of pins that will, in the surgeon's judgment, leave an appropriate portion of the cortical shell adjacent the apex of the bone segment to be removed to act as a hinge about which the tibia can be bent.” (Col. 2, ln. 68).

An adjustment member 28 is adjustably mounted in the guide block 20 by being threadably engaged therewith for movement in a direction generally parallel to the first pair of guide bores 22. The adjustment member 28 has a conical end surface 30 adapted to engage the surface of a bone positioned on the side of the block 20 toward which the bores 22 and 24 converge, and has a knurled manually engageable knob 32 at its end opposite its end surface 30 by which the spacing between the end surface 30 and block locating surface 26 may be adjusted...” (Col. 4, ln. 34).

“...the newly severed surfaces 55 are secured in face-to-face relationship as by staples 56, plates or other means, and the newly severed surfaces of the tibia 40 are allowed to heal together.” (Col. 5, ln. 67).

Thus, Mains is not directed to replacing at least a portion of a patient's knee, but rather, simply removing a wedge of bone to correct the knee angle. Accordingly, Mains does not make an incision smaller than a portion to be replaced, and does not disclose a limited incision for the purpose of removing bone.

While an intramedullary device is not used or suggested in Mains, the purpose for resecting bone in Mains is distinguished from replacing a portion of the joint, and the accuracy of alignment is accordingly less critical. Indeed, the placement of the guide block is not discussed at all in Mains, and accuracy is limited to the “surgeon's judgement” in determining the portion of cortical section to be removed. Further, pins are positioned “generally parallel” to the plane of the knee, and “generally parallel” to or angled “generally away” from the plane of the knee.

While an adjustment knob is provided in Mains, it functions only to change an angle between pairs of pins, and does not address the initial positioning of the block against the bone.

Accuracy is in fact less critical in Mains, because a precise fit between an implant

replacement portion and the cut knee is not required. Rather, the knee bone is merely hinged together and staped in place. An ill fitting replacement portion will eventually break free, causing damage to the associated bone, pain, and or ultimate failure of the implant. In contrast, the mating surface of bone in Mains knit together in a natural healing process of bone on bone. Thus, Mains is directed to an entirely different problem, and is thus clearly non-analogous art.

Moreover, it is illogical to combine Mains with a reference directed to replacing portions of a joint, such as Burkinshaw, as the problems addressed are different, and the methods of Mains are insufficiently accurate or relevant to replacing a portion of a joint.

In summary, neither Burkinshaw or Mains discloses, suggests or teaches:

replacing a portion of a knee through an incision sized smaller than the portion of the knee to be replaced;

determining a position of a cutting guide using references derived independently from an intramedullary device;

positioning a cutting guide using such determined position;

making an initial cut on an unresected femur using the cutting guide—Mains is directed only to removing a part of the tibia, and is not related to joint replacement; and

positioning without the use of an IM or EM rod;

a cutting guide customized for a single bone, discarded as no longer useful once the bone for which it has been customized has been changed.

Accordingly, Applicant respectfully submits that independent claims 1, 13, and 19 are patentable over Burkinshaw in view of Mains. As claims 2, 4-8, 10-12, and 31-33 depend from claim 1; claims 14-18, 34 and 39 depend from claim 13; and claims 20, 22-26, 28-30 and 35-37 depend from claim 19, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the remaining dependent claims are allowable over the cited references at least for the same reasons.

In light of the foregoing, Applicant requests reconsideration and withdrawal of this section 103 rejection.

New Claims

New claims 40-42 further clarify the invention. Support for the claims may be found throughout the specification, and particularly at least as follows: for claim 40, at paragraph [0608] et seq. , and Fig's. 59-66; for claim 41, at paragraph [0494] et seq., and Fig. 54; and for claim 42 at paragraph [0296] et seq., and Fig. 31. No new matter has been added.

Applicant respectfully submits that claims 40-42 are not suggested or taught by the prior art, and allowance is therefore respectfully requested.

Conclusion

In the light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fees are believed to be due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A03-012C).

Respectfully submitted,

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